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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,892	05/16/2005	Vibhudutta Awasthi	21105.0009U2	8484

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,892	AWASTHI ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6 and 8-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6 and 8-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/27/05, 11/10/05 and 07/10/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of IDS filed on 05/27/05, 11/10/05 and 07/10/07 is acknowledged.

Election/Restriction

Applicants election of Group 1, claims 1-27 in response to Restriction /Election mailed on 10/18/07 is acknowledged.

Applicants election of the following species filed on 10/18/07 is also acknowledged.

For the lipid compound, Applicant elected the species distearoyl phosphatidylcholine.

For the steroid compound; Applicant elected the species cholesterol.

For the encapsulated compound; Applicant elected the species stroma-free hemoglobin.

For the hydrophilic compound, Applicant elected the species polyethylene glycol.

For the starch compound, Applicant elected the species pentastarch.

Examiner acknowledges applicants election of species for distearoyl phosphatidylethanolamine as the anchoring component and dimyristoyl phosphatidylglycerol as the anionic lipid.

Examiner acknowledges applicants election of species as **without traverse filed on 10/18/07.**

Claims 3, 7 and 28-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/18/07.

Accordingly, claims pending in the prosecution are claims **1-2, 4-6 and 8-27.**

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation “anchoring compound”. The nature of the anchoring compound is not clear. Examiner suggests reciting appropriate compound since the claim recites a product between hydrophilic and anchoring compound.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-2, 4-6, 8-20 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (US Pg PUB 2005/0123617 A1) in view of Boch et al. (US PG pub. 2002/0156062 A1) and further in view of Yuda et al. (Bio. Pharm. Bull. (19

(10) 1347-1351 (1996) and Carrion et al. (Chemistry and Physics of Lipids, 113 (2001) 97-110).

Chang et al. discloses a polymeric nanocapsule composition, adaptable for encapsulation of an agent of therapeutic interest for enhancing the in vivo circulation time and use thereof (abstract). The biodegradable polymer may encapsulate hemoglobin, enzymes, polypeptides etc. (see page 1, paragraph [0017]). The polymer used is polyethylene glycol and polylactic acid polymer (see paragraph [0031]). Polylactic acid is prepared from phospholipid such as distearoyl phosphatidylcholine or DSPG (see page 4, paragraph [0061]). On page 4, paragraph [0061} under materials and methods, Cheng et al. disclose distearoyl phosphatidylcholine and cholesterol. Stroma free hemoglobin preparation is shown on page 4, paragraph [0064]). The concentration of hemoglobin is shown to be between 10 to 15g hemoglobin/dl. Example 1 discloses nanocapsule preparation. The use of submicron phospholipid cholesterol microcapsules increased the survival time of hemoglobin in the circulation (Djordjevich et al.) is disclosed on page 1, paragraph [0007]. The nanocapsules are suspended in ascorbic acid or glutathione (see paragraph [0148]).

The reference does not disclose anionic lipid dimyristoyl phosphatidylglycerol. Boch et al. teaches drug delivery system for hydrophobic drugs (title). The reference discloses that Phosphatidyl glycerols (PGs) may also be present in the MA of the invention. Examples of such PGs include dimyristoyl phosphatidyl glycerol (DMPG), DLPG and the like. The incorporation of such PGs may be used to contribute to the

stabilization of micelles. Other types of suitable lipids that may be included are phosphatidyl ethanolamines (PEs), phosphatidic acids (PAs), phosphatidyl serines, and phosphatidyl inositols (see paragraph [0066]).

It would have been obvious to incorporate dimyristoyl phosphatidyl glycerol (DMPG) in the composition forwarded by Chang et al. because boch et al. teaches that addition of such lipids add stability to the liposomal miceles.

With respect to the post insertion compound, Chang et al. and Boch et al. do not disclose the anchoring compound distearoyl phosphatidylethanolamine, however, Chang et al discloses the hydrophilic compound polyethylene glycol and Cholesterol (anchoring compound).

Yuda et al. disclose prolongation of circulation time of liposomes by various derivatives of polyethyleneglycols and their great potential in drug delivery system (title and 1st paragraph). Synthesis of DSPE and PEG has been shown on page 1348 under materials and methods. Carrion et al. disclose preparation of long circulating immunoliposomes using PEG-cholesterol conjugates (title). Therefore, based on the teachings of Yuda et al. and Carrion et al. it would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate post insertion compound comprising the product of hydrophilic polyethylene glycol and anchoring compound distearoyl phosphatidylethanolamine in the liposomal formation of Chang et al. and Boch et al. with a resonable expectation of success because Yuda et al. and Carrion et al. disclose and provide guidance as to how to increase circulating

time of liposomes by using PEG conjugates and make them more stable in drug delivery process.

6. Claims 21-24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (US Pg PUB 2005/0123617 A1) in view of Boch et al. (US PG pub. 2002/0156062 A1), Yuda et al. (Bio. Pharm. Bull. (19 (10) 1347-1351 (1996), Carrion et al. (Chemistry and Physics of Lipids, 113 (2001) 97-110) and further in view Hsia et al. (US 2002/0013263 A1) and Roberts et al. (Drugs 1998 (55)1,621-630 of record).
The disclosed references do not disclose plasma expanders.
Hsia et al. discloses a physiologically compatible solution of conjugated hemoglobin produced by forming a conjugate of hemoglobin and a biocompatible macromolecule used as a plasma expander. Plasma expanders, such as dextran, polyoxyethylene hydroxylethyl starch are used to increase the circulation half life of hemoglobin in the body. Roberts et al. similarly disclose dextrans ,albumin and pentastarch as plasma expanders (see the whole article and page 626, column 2, 2nd paragraph).
It would have been obvious to the one of ordinary skilled in the art at the time of the invention to incorporate plasma expander such as pentastarch in the combined teachings of the references disclosed above because pentastarch has been shown to lead to greater expansion of intravascular space.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612/

/Snigdha Maewall/

Examiner, Art Unit 1612